REMARKS

The Examiner rejected claims 1-7 and 16 as allegedly not complying with 35 U.S.C. 112, first paragraph, written description requirement. Specifically, the Examiner acknowledged the fact that specific PDE4 inhibitors were known. However, the Examiner alleged that this fact is not probative because the applicants have not provided evidence that the PDE4 inhibitors known in the art as "specific PDE4 inhibitors" are in fact "specific", and do not inhibit Type 1 or Type 3 PDEs.

Applicants respectfully submit a third Declaration by Dr. Lerner under 37 C.F.R. 1.132 ("3rd Lerner Declaration"). Dr. Lerner clearly explains that based on the level of the skill in the art and the widely available knowledge about PDEs and their inhibitors in general and PDE4 specific inhibitors particularly, and in view of the specification, wherein the PDE4 specific inhibitor is also defined, a skilled artisan knows that the class of compounds useful according to the invention is specific PDE4 inhibitors (par. 18 of the 3rd Lerner Declaration).

In looking for specific PDE4 inhibitors, one skilled in the art looks for inhibitors that do not affect other PDEs (see, e.g., pars. 13-14 of the 3rd Lerner Declaration). This is naturally done by comparing the effect of a specific inhibitor to the activity of the various PDEs (Id.). If an effect is only shown on PDE4, and not other types, then the terms "PDE4 inhibitor", "selective PDE4 inhibitor" or "specific PDE4 inhibitor" are used (pars. 3, 4, and 10 of the 3rd Lerner Declaration. These belong to a completely different class of compounds from compounds that are non-specific PDE inhibitors, such as theophylline (par. 11 of the 3rd Lerner Declaration).

Moreover, Dr. Lerner shows that it has been unequivocally confirmed that the compounds that were known as "specific PDE4 inhibitors" at the time of filing the application, did not indeed inhibit other PDEs, such as PDE1, PDE2, PDE4, or PDE5 (see, e.g., pars 15-16 of the 3rd Lerner Declaration).

The Examiner contended that "to provide adequate written description and evidence of possession of **a claimed genus**, the specification must provide sufficient distinguishing characteristics of the genus" (2nd and 3rd line from the bottom of page 2, of the July 18, 2008

Office Action, emphasis added). The Examiner also contended that the specification does not provide adequate written description because the specification describes "two species of **the claimed genus**" (page 3, second full par. of the July 18, 2008 Office Action, emphasis added). The Examiner asserted that there is "little more than a semantic distinction without a difference" in claiming a genus of PDE4 inhibitor compounds and claiming a method of treating CLL using a known class of PDE4 specific inhibitors (page 4, lines 3-5).

As already explained before, contrary to what the Examiner appears to be arguing, the pending **claims are not directed to a genus of PDE4 inhibitors**. The claims are directed to a method for treating CCL using PDE4 specific inhibitors. Applicants fail to understand why the Examiner considers that there is only a "semantic distinction" between a claim directed to a novel compound and a claim directed to a novel method of use for a well known class of compounds.

As noted in the Amendment dated April 25, 2008, the Federal Circuit Court has specifically dealt with the **difference** between claiming **a class of unknown compounds** and claiming a **method of using known compounds** in *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). It is the latter situation, namely a method of using known compounds, that the present claims are directed to. In *Capon v. Eshhar*, the claims were directed to a chimeric DNA encoding a membrane bound protein. The court held that the U.S. PTO Board of Appeal erred in stating that 35 U.S.C. 112, first paragraph, written description was not met by a "reference to contemporary and/or prior knowledge in the art of the structure, formula, chemical name, or physical properties of many protein domains, and/or sequences which encode many protein domains." Thus, in *Capon v. Eshhar*, the court specifically reversed the Board's decision that 35 U.S.C. §112 imposed a per se rule requiring recitation in the specification of the nucleic acid sequence of a claimed DNA, when the sequence was already known in the field.

Like in *Capon v. Eshhar*, the specific PDE4 inhibitors used in the method of treating CLL of the present invention were a well known class of compounds. It is the novel use of these known compounds that is the subject of the present claims. As already stated before, the specification provides a definition for specific PDE4 inhibitors that clearly sets forth the class of

compounds that can be used in the invention (see, for example, page 4, lines 6 – 13; page 6, line 15; page 7 – line 13). Moreover, the Examiner acknowledged that it is a fact that the class of PDE4 inhibitors were well known at the time the application was filed (see, page 4, line 11 of the July 18, 2008 Office Action). The Examiner questioned the "specificity" of these "specific" PDE4 inhibitors. However, as discussed above, Applicants have herewith provided additional scientific evidence of the fact that the class of "specific PDE4 inhibitors" were indeed known to be PDE4 specific (3rd Declaration of Dr. Lerner).

Accordingly, Applicants respectfully submit that claims 1-7 and 16 fully comply with 35 U.S.C. 112, first paragraph, written description requirement, and that the rejection should be withdrawn.

In view of the foregoing, Applicant respectfully submits that all claims are in condition for allowance. Early and favorable action is requested.

In the event that any additional fees are required, the Commissioner is authorized to charge Nixon Peabody LLP Deposit Account No. 50-0850.

Respectfully submitted,

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